

| Device | Metasul (Zimmer) | Ring (Downs Surgical) New & Explants 17 – 26 years, Total 7 parts Heads & cups | McKee (Howmedica) New & Explants 4 parts not known period but clearly a number of years |
|--|---|--|---|
| 510k Number | | | |
| Femoral Heads: | | | |
| Material | Wrought Forged High-Carbon CoCrMo (ASTMF- 75)* Internal spec Protasul WF21 | Cast High Carbon range 0.23 – 0.44% Mostly “As cast”, i.e. No post cast heat treatments High Carbon is above 0.24%, Low would be approx 0.025% | Cast High Carbon range 0.27% x3 “As cast”, i.e. No post cast heat treatments |
| Diameter | 28 & 32 mm | Nominal 40mm or 1 9/16 inch (often both sizes engraved) Some were Nominal 41mm | 40mm Nominal There wear also some 35mm diameter hips (1 3/8”) produced |
| Sphericity | <5 microns | Variations from 2 – 50µm depending on wear state. Start rounds also varied but generally about 10 µm | Same as Rings with wide variations |
| Surface finish | 0.005 microns | 0.017 – 0.018µm Ra | 0.004µm Ra |
| Taper Sleeve Adapters Taper Geometry | Femoral heads: 12/14 internal taper Wrought Forged High Carbon CoCrMo alloy (ASTM F-75) | One piece construction of stem with head | One piece construction of stem with head |
| Taper/Neck Lengths | 12/14. -4, 0, +4, +8 | N/A | N/A |
| Acetabular Component: | Metal liner in an UHMWPE outer (sandwich design) | One piece screw stem cup, uncemented | One piece, cemented cup with short pegs as cement spacers |
| Material | Wrought Forged High- | Cast High Carbon range 0.23 – 0.44% | Cast High Carbon range 0.22 – 0.29% x2 |

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| | Carbon CoCrMo (ASTMF- 75)* Internal spec Protasul WF21 | “As cast”, i.e. No post cast heat treatments | “As cast”, i.e. No post cast heat treatments But one has post cast minimal heat treatment. |
| Method of Fixation (coating type) | Various Zimmer acetabular shells such as Allofit (roughened Ti surface with macro ridges) | None, fine shot blast CoCr surface with mechanical fixation from the long screw on the dome of the cup. | Cemented cup with short pegs as cement spacers |
| Outer diameter | 44-64 in 2mm increments (typical) | 45 – 48mm | Approximately 50 and 45mm. |
| Inner diameter | 28 & 32mm | Nominal 40mm or 1 9/16 inch (often both sizes engraved) Some were Nominal 41mm Cups generally measure this size with heads smaller by the clearance amount | 40mm Nominal There wear also some 35mm diameter hips (1 3/8”) produced |
| Sphericity | <5 microns | Generally about 10µm start roundness, some had a central dimple | Generally about 10µm start roundness, some had a central dimple (slightly flattened area at the pole) |
| Surface finish | 0.005 microns | 0.007 – 0.013µm Ra | 0.009 – 0.21 in scratched area |
| Diametrical clearances and tolerances** | Radial clearance 35-75 microns | 150 – 300µm on known explant pairs but some parts this cannot be verified | 127 - 386µm from literature review. |
| Range of motion | | 125 degrees | Not measured |
| Wear rates | 28mm 5.6 microns per million cycles | 0.8 – 2.8µm linear per year average for life of 17 – 26 years Approx average 0.5 – 1mm ³ per year | Not known on these parts. Approximately 2-10mm ³ per year (Kothari et al, CORR 329S) |
| Rotational frictional torque measurements | Not available | Not available | Not available |
| Flexion/extension | 28mm – 4Nm (internal | Not available | Not available |

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| frictional torque measurements | pendulum test) 28mm friction from a hip simulator test 3Nm initially dropping to 2Nm after 1 million cycles | | |
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- *Please define what is meant by a high carbon or a low carbon alloy and please specify a standard that must be met to certify the material is high carbon. Also, when completing this table, please ensure that the definition provided in response to this item is applied to each entry for each head and cup material.
- ** For the diametrical clearances please include the least and most tolerances for both the head and liner. In addition, please do not group all sizes together. Please list each size and each minimum and maximum clearance range for each diameter separately.

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| Surface finish | 0.017 – 0.018µm Ra | 0.004µm Ra | |
| Taper Sleeve Adapters Taper Geometry | One piece construction of stem with head | One piece construction of stem with head | |
| Taper/Neck Lengths | | | |
| Acetabular Component: | One piece screw stem cup | One piece | |
| Material | Cast High Carbon range | Cast High Carbon range | |

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| Method of Fixation (coating type) | None | | |
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| Inner diameter | Nominal 40mm or 1 9/16 inch (often both sizes engraved) Some were Nominal 41mm Cups generally measure this size with heads smaller by the clearance amount | | |
| Sphericity | Generally about 10µm start roundness, some had a central dimple | Generally about 10µm start roundness, some had a central dimple | |
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